K041948

AUG 11 2004

American Medical Systems

## 510(k) Summary

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| **Submitter:** | American Medical Systems<br>10700 Bren Road West<br>Minnetonka, Minnesota 55343 |
| **Date Prepared:** | July 19, 2004 |
| **Contact:** | Kristyn M. Benson<br>Sr. Regulatory Affairs Specialist |
| **Proprietary Name:** | SPARC™, MONARC™, BioArc SP™, and BioArc TO™ Sling Systems |
| **Common Name:** | Surgical Mesh |
| **Device Product Code & Classification:** | Class II; FTL |
| **Predicate Device:** | SPARC™ Sling System (K021263)<br>MONARC™ Sling System (K023516)<br>BioArc SP™ Sling System (K030123)<br>BioArc TO™ Sling System (K040538) |

**Device Description:**
The SPARC™, MONARC™, BioArc SP™, and BioArc TO™ Sling Systems are sterile, single use procedure kits that consist of two stainless steel, curved needle passers (also known as insertion tools); AMS polypropylene sling mesh and suture; and two plastic sheaths that cover and protect the sling mesh during placement.

**Intended Use:**
The SPARC™, MONARC™, BioArc SP™, and BioArc TO™ Sling Systems are intended for the placement ofa pubourethral sling for the treatment of female stress urinary incontinence (SUI) resulting from urethral hypermobility and/or intrinsic sphincter deficiency.

**Statement of Technological Comparison:**
The risk analysis and the verification/validation activities reported in this Special 510(k) application substantiate equivalence to the predicate devices and did not raise any new questions of safety or efficacy.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 1 1 2004

Ms. Kristyn M. Benson
Sr. Regulatory Affairs Specialist
American Medical Systems
10700 Bren Road West
Minnetonka, Minnesota 55343

Re: K041948
Trade/Device Name: SPARC™, MONARC™, BioArc SP™, and BioArc TO™ Sling Systems
Regulation Number: 21 CFR 878.3300
Regulation Name: Polymeric surgical mesh
Regulatory Class: II
Product Code: FTL
Dated: July 19, 2004
Received: July 20, 2004

Dear Ms. Benson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

**INDICATIONS FOR USE STATEMENT**

**510(k) Number:** (Pending) K041948

**Device Name:** SPARC™, MONARC™, BioArc SP™, and BioArc TO™ Sling Systems

**Indications for Use:**

The SPARC™, MONARC™, BioArc SP™, and BioArc TO™ Sling Systems are intended for the placement ofa pubourethral sling for the treatment of female stress urinary incontinence (SUI) resulting from urethral hypermobility and/or intrinsic sphincter deficiency.

Prescription Use X AND/OR Over-the-Counter-Use _____
(Per 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE—CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost

**(Division Sign-Off)**
**Division of General, Restorative, and Neurological Devices**

**510(k) Number** K041948